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(54) SUSTAINED RELEASE NIFEDIPINE PHARMACEUTICAL FOR APPLICATION TO ORAL MUCOSA**(57)Abstract:**

PURPOSE: The titled pharmaceutical, consisting of a rapidly soluble layer consisting of nifedipine and polyvinylpyrrolidone (PVP) of specific composition and a delayed dissolution layer consisting of the nifedipine, PVP and polyacrylic acid, and having ready absorbability and prolonged action of the nifedipine useful as an antianginous agent.

CONSTITUTION: A pharmaceutical consisting of two layers of a rapidly soluble layer consisting of a solid solution of nifedipine and polyvinylpyrrolidone (PVP) and an excipient and a delayed dissolution layer consisting of the solid solution of the nifedipine, PVP and polyacrylic acid and a salt thereof. The pharmaceutical is characterized in that the content of the PVP in the rapidly soluble layer is 20W80wt% and the weight ratio between the solid solution component and the polyacrylic acid in the delayed dissolution layer is 5:95W95:5. The solid solution of the nifedipine dissolved in the PVP in the solid state enhances the absorption of the slightly soluble nifedipine, and the polyacrylic acid contributes to the sustained release and adhesive properties. The dissolution of the nifedipine in saliva is kept constant for a long time, and the blood concentration is kept constant for a long time.

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M1 M113 M210 M211 M240 M272 M282 M320 M413 M431 M510 M521 M531 M540
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AB - J61015829 Sustained release nifedipine preps. of two-layer structure
to be applied to oral mucous membrane, consist of (I) a
rapid-dissolving layer comprising solid soln. of nifedipine in
polyvinyl pyrrolidone and an excipient, and (II) a
dissolution-retarding layer comprising solid soln. of nifedipine in
polyvinyl pyrrolidone and polyacrylic acid (and/or a pharmaceutically
acceptable salt), wherein the amt. of the polyvinyl pyrrolidone in the
rapid-dissolving layer (I) is 20 to 80% of the total weight of that
layer and wherein the weight ratio of the solid soln. of nifedipine in
polyvinyl pyrrolidone in the dissolution-retarding layer (II) to the
polyacrylic acid (and/or a pharmaceutically acceptable salt) is in the
range of 5:95 to 95:5.
- USE/ADVANTAGE - Nifedipine dissolves out into saliva at practically a
constant rate for long periods, thus ensuring a constant level in the
blood for long periods.
IW - SUSTAINED RELEASE NIFEDIPINE COMPOSITION ORAL MUCOUS MEMBRANE COMPRISE
RAPID DISSOLVE LAYER POLYVINYL PYRROLIDONE EXCIPIENT DISSOLVE RETARD
LAYER POLYVINYL PYRROLIDONE POLYACRYLIC ACID
IKW - SUSTAINED RELEASE NIFEDIPINE COMPOSITION ORAL MUCOUS MEMBRANE COMPRISE
RAPID DISSOLVE LAYER POLYVINYL PYRROLIDONE EXCIPIENT DISSOLVE RETARD
LAYER POLYVINYL PYRROLIDONE POLYACRYLIC ACID
NC - 001
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Ti - Sustained release nifedipine compsn. for oral mucous membrane -
comprises rapid-dissolving layer of vinyl] pyrrolidone and excipient
and dissolution retarding layer of vinyl] pyrrolidone and acrylic]
acid